**Department of Veterans Affairs** **VHA DIRECTIVE 99-033**
**Veterans Health Administration**
**Washington, DC 20420** **July 22, 1999**

# INSPECTION OF LABORATORIES PERFORMING RADIOBIOASSAY TESTING

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes the policy and procedures for the inspection of laboratories performing radiobioassay testing. Radiobioassay testing includes tests that involve the in-vivo administration of radioactive materials to a patient and the subsequent measurement of radioactivity in body fluids.

**2. POLICY:** As required by Public Law 102-139, VHA laboratory testing will meet the regulations (Title 42 Code of Federal Regulations (CFR), Part 493) implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). All laboratory testing comes under the oversight of the clinical laboratory.

**3. ACTION:** All testing sites that perform laboratory testing for patient care will maintain current accreditation by an appropriate, nationally recognized, Health Care Financing Administration (HCFA) "deemed" accrediting body. Ancillary testing sites outside the physical limits of the main VA medical laboratory facilities performing radiobioassays will be included as part of the main laboratory accrediting process or will maintain current accreditation by an appropriate, nationally recognized, HCFA "deemed" accrediting body. The CLIA Enforcement Officer and appropriate Department of Veterans Affairs (VA) Pathology Regional Commissioner will provide oversight and enforcement of the policies defined in this directive.

a. Each Veterans Integrated Service Network (VISN) will ensure that all laboratories and individuals performing radiobioassays used for the diagnosis and/or guiding treatment of patients are in compliance with the policies of 42 CFR Part 493 and this directive.

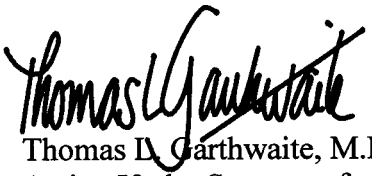
b. The Chief, Nuclear Medicine, Imaging, and Diagnostic Services will ensure that nuclear laboratories that perform radiobioassay testing maintain current accreditation by an appropriate, nationally recognized, HCFA "deemed" accrediting body.

**4. REFERENCES:** Title 42 CFR Sections 493.1263 and 493.1201-493.1221.

**5. FOLLOW-UP RESPONSIBILITY:** The Program Director, Nuclear Medicine Service, Diagnostic Services SHG (115B), is responsible for the contents of this directive**.**

**6. RESCISSION:** None. This VHA Directive expires July 31, 2004.

S/ Robyn Nishimi, Ph.D. for



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**THIS VHA DIRECTIVE EXPIRES JULY 31, 2004**